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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/405,504	09/23/1999	ANDREAS STAHL	WHI9721P3MC2	9550

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EXAMINER

WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 05/12/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/405,504

Applicant(s)

STAHL ET AL.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 82-84,97-103,105-113,115,116 and 118-139 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 82-84,97-103,107-113 and 118 is/are allowed.
- 6) ☒ Claim(s) 105,106,115,116 and 124-139 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's amendment submitted after final on 31 January 2003 has been entered. Claims 1-81, 85-96, 104, 114 and 117 have been cancelled.

Claims 82-84, 97-103, 105, 106, 107-113, 115, 116 and 118-139 and the nucleotides encoding SEQ ID NO: 24 are under examination in the instant application.

Claim Objections/Rejections

35 USC § 112, first paragraph-Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 105, 106, 115, 116 and 124-139 are not enabled under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for use of the nucleic acid encoding the full length peptide, does not reasonably provide enablement for various protein forms of *FATP*, wherein the DNA sequence is at least 95% identical to the disclosed nucleic acid sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims are directed to use of a polynucleotide encoding a *FATP* transporter polypeptide to search for inhibitors of the transporter. The specification discloses a *FATP* transporter encoded by the DNA of SEQ ID NO: 24 and 46, having an amino acid sequence shown in SEQ ID NO: 25, as well as methods for recombinantly expressing SEQ ID NO: 25. The scope of the patent protection sought by the Applicant as defined by the claims fails to correlate reasonably with the scope of enabling disclosure set forth in the specification for the following reasons:

The specification discloses an enabled utility for the fatty acid transporter encoded by the DNA of SEQ ID NO: 24 and 46, as to be used to identify inhibitors of the transporter. However, there is no discussion, or working examples disclosed in the instant case, as to what amino acids are necessary to maintain the functional characteristics of the claimed polynucleotides encoding the *FATP* transporter polypeptide. The instant case claims altering as much as 5% of the polynucleotide encoding the polypeptide of SEQ ID NO: 25. However, the art shows that receptor families have members with high structural similarities but disparate functions. For example, Smith et al. (1997, Nature Biotechnology 15:1222-1223) demonstrate that there are

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numerous cases in which proteins having very different functions share structural similarity due to evolution from a common ancestral gene. Brenner (1999, Trends in Genetics 15:132-133) argues that accurate inference of function from homology must be a difficult problem since, assuming there are only about 1000 major gene superfamilies in nature, then most homologs must have different molecular and cellular functions. Bisson, *et al* (1993, Crit Rev Biochem Mol Biol, 28:259) studied yeast transporter knockout phenotypes, and found little correlation between homology and the substrate transported. For example, they found that yeast transporters *Gal2* and *Hxt4* displayed 83.7% homology, but *Gal2* appears to transport Galactose, while *Hxt4* appears to transport Glucose (based on knockout phenotype- compare Table 1 and Table 2A). Similarly, Liang *et al* found that only a few amino acid substitutions in glucose transporters can change substrate specificity dramatically (1998, Liang, H., *et al*, Mol. Cell. Biol. 18(2): 926). Finally, Atsushi, *et al* (1996, J. Biol. Chem. 271: 30360) found that changing select amino acids in an acyl-CoA synthetase enzyme -less than 3% of the total residues- resulted in a functional fatty acid transporter (see Fig. 8).

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Due to the large quantity of experimentation required to determine how to use the variants of SEQ ID NO:25, the lack of direction or guidance in the specification regarding same

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(e.g., what amino acids are necessary to maintain the functional characteristics of the polypeptide encoded by the claimed polynucleotide of SEQ ID NO: 24 and 46), the lack of working examples to variants of SEQ ID NO: 25, the state of the art showing the unpredictability of function based on structural similarity of receptor proteins, and the breadth of the claims which embrace innumerable variants of SEQ ID NO: 25, undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

Conclusion:

Claims 105, 106, 115, 116 and 124-139 are rejected for the reasons cited above. Claims 82-84, 97-103, 107-113 and 118 are allowable.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

4/30/03


GARY KUNZ
SUPERVISORY PATENT EXAMINER
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